JAN 1 6 2004

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR part 807.92.

Submitter: NovoSci™ Corp
2828 N. Crescent Ridge Dr.
The Woodlands, Texas 77381

Contact: LeAnn Latham
Regulatory Affairs Manager
Phone: 281-363-4949

Device trade name:	NovoSci™ Tubing and Connectors with NovoCoat™
Common name:	Cardiopulmonary bypass tubing and connectors
Classification name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, Fitting, Cardiopumonary Bypass
Classification:	Class II
Panel:	Cardiovascular (CV)
Product code:	DWF, DTL
Regulation Number:	870.4210, 870.4290
Predicate Device:	NovoSci™ Duraflo treated tubing and connectors

Device Description:

The NovoSci™ tubing and connectors treated with NovoCoat™ are sterile, single use only, disposable devices. They are used to connect cardiopulmonary bypass components used during surgery procedures requiring extracorporeal support. When used on devices for cardiopulmonary surgery, the NovoCoat™ treatment improves blood compatibility of non-biological surfaces in the extracorporeal circuit.

NovoSci™ tubing is polyvinyl chloride (PVC) tubing available in various sizes. The NovoSci™ connectors are polycarbonate in various configurations such as straight, reducing, "Y" , with or without luer ports.

Indications for Use:

The NovoSci™ tubing and connectors with NovoCoat™ treatment are indicated for use in cardiopulmonary surgical procedures requiring extracorporeal support for periods up to 6 hours.

Statement of Technological Characteristics Comparison:

The NovoSci™ NovoCoat™ treated tubing and connectors are substantially equivalent to the currently marketed NovoSci™ tubing and connectors with Duraflo treatment.

Non-clinical testing

Biocompatibility, in-vitro and performance testing were performed to demonstrate equivalence. These tests include: blood damage, bond strength, hardness, leak test, pump life.

Conclusions:

This data supports that the NovoSci™ NovoCoat™ treated tubing and connectors are substantially equivalent in safety and efficacy to the currently marketed NovoSci™ Duraflo treated tubing and connectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2004

NovoSci™ Corp.
c/o Ms. LeAnn Latham
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

Re: K033328
NovoSci™ Tubing and Connectors with NovoCoat™
Regulation Number: 21 CFR 870.4290 and 4210
Regulation Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTL and DWF
Dated: October 15, 2003
Received: October 16, 2003

Dear Ms. Latham:

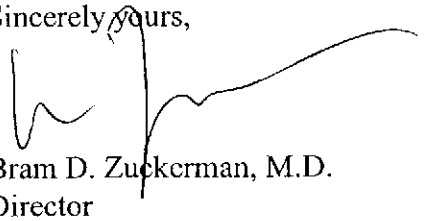
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033328

Indications for Use

510(k) Number (if known) K033328

Device Names: NovoSci™ tubing and connectors with NovoCoat™ treatment

Indications for Use:

The NovoSci™ NovoCoat™ treated tubing and connectors are indicated for use in cardiopulmonary surgical procedures requiring extracorporeal support for periods up to 6 hours.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033328

X prescription